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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-42

March 6, 2001

Thomas E. Turner, Owner
Glenn's Wholesale Sandwiches
419 E. Donegan Avenue
Kissimmee, FL 34744

Dear Mr. Turner:

We inspected your firm at the above address on February 16 and 22, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm does not have a HACCP plan for tuna salad sandwiches to control the food safety hazard of Pathogen Growth and Toxin Formation.

You must retain records at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products to comply with 21 CFR 123.9(b)(1). However, your firm's process monitoring and sanitation control records for tuna salad sandwiches were only retained for two months.

In addition, we note that all of your finished product sandwiches with the exception of tuna salad are misbranded within the meaning of Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act in that the label fails to bear the common or usual name of each ingredient used in the product. For example the bread and cheese each contain numerous ingredients, which are not listed on your label [21 CFR 101.4(b)(2)]. This violation was previously brought to your attention in our letter to you dated April 30, 1999, a copy of which is attached for your reference.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a HACCP plan for your tuna salad sandwiches and copies of revised sandwich labeling that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Ken Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton,
Director, Florida District

Enclosure